AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Appellants:	Dusan Pavcnik Josef Rösch Frederick Keller	)	
		)	Group Art Unit:
Serial No.:	09/849,044	)	3738
Filed:	May 4, 2001	)	
For:	ENDOVASCULAR STENT GRAFT	)	Examiner: Alvin J. Stewart
Docket No.:	3006-1658	)	

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on:

August 19, 2005
Date of Deposit

Kenneth A. Gandy
Name of Registered Representative

Signature

August 19, 2005
Date of Signature

BRIEF FOR PAVCNIK, RÖSCH, AND KELLER

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants appeal from the final rejection dated October 19, 2004 of claims 1 and 3-9 of this application. This appeal applies to each of these claims.

Real Party in Interest

Cook Incorporated is the Real Party in Interest.

Related Appeals and Interferences

There are no related appeals or interferences.

Status of Claims

Claims cancelled: 2, 10, and 11

Claims pending: 1 and 3-9

Claims on appeal: 1 and 3-9

Status of Amendments

No amendments were presented subsequent to the final office action forming the basis for appeal.

Summary of the Claimed Subject Matter

The subject matter of the independent claims is summarized below with reference to the drawings and specification. Numeric references are to Figures 1 and/or 2 unless otherwise indicated and are followed by page and line numbers for associated text.

Independent claim 1 is directed to a stent graft (10; pg. 4, line 11) comprising at least one stent (16; pg. 4, lines 14-15) having a proximal end (26; pg. 6, line 28) and a distal end (34; pg. 6. line 28) and having a lumen extending therethrough between the proximal and distal ends. The stent graft includes a covering (14; pg. 4, line 12) of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue (pg. 4, line 27 through pg. 6, line 1; pg. 9, line 26 through pg. 10, line 4), secured (pg. 6, line 6 through pg. 7, line 26) to the at least one stent and extending therealong between the proximal (26) and distal (34) ends, wherein the covering (14) is a sleeve (pg. 4, lines 12-13) that initially has a length about equal to twice the length of the at least one stent (16). A first portion (28; pg. 6, lines 19-20) of the sleeve extends along and complements inside surface of the at least one stent (16), and a second portion (30; pg. 6,

lines 19-20) of the sleeve is folded back over a proximal end (26) of the at least one stent and then along an outside surface of the at least one stent (16) to the distal end (34) thereof (pg. 6, lines 12-23). The first portion (28) and the second portion (30) of the sleeve are secured to at least the distal end (34) of the at least one stent (16).

Independent claim 3 is directed to a stent graft comprising at least one stent (16) having a proximal end (26, pg. 6 line 28) and a distal end (34, pg. 6, line 28) and having a lumen extending therethrough between the proximal and distal ends. The stent graft includes a covering (14; pg. 4, line 12) of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue (pg. 4, line 27 through pg. 6, line 1; pg. 9, line 26 through pg. 10, line 4), secured (pg. 6, line 6 through pg. 7, line 26) to the at least one stent and extending therealong between the proximal (26) and distal (34) ends, wherein the covering is a sleeve (pg. 4, lines 12-13) that initially has a length about equal to twice the length of the at least one stent (16). A first portion (28; pg. 6, lines 19-20) of the sleeve extends along and complements inside surface of the at least one stent (16), and a second portion (30; pg. 6, lines 19-20) of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent (16) to the distal end (34) thereof (pg. 6, lines 12-23). The stent graft further comprises a plurality of stents (see multiple stents 16) connected together to form a stent frame (12) with lumens of the respective stents coaligned to form a common continuous lumen extending from a distal stent frame end (34) to a proximal stent frame end (26), and the covering 14) extending therealong between the proximal (26) and distal (34) stent frame ends.

Issues on Appeal

1) Whether claims 1 and 7-9 are unpatentable under 35 U.S.C. § 103 (a) over Babbs (WO 98/25544).

2) Whether claims 3-6 are unpatentable under 35 U.S.C. § 103 (a) over Babbs (WO 98/25544) in view of Douglas (U.S. Pat. No. 6,090,128).

3) Whether claims 1 and 3-9 are unpatentable under 35 U.S.C. § 103 (a) over Gregory (U.S. Pat. No. 5,990,379) in view of Douglas (U.S. Pat. No. 6,090,128).

Grouping of Claims

For purposes of this appeal:

1) Regarding Issue 1, claims 1 and 7-9 stand and fall together.

2) Regarding Issue 2, claims 3-6 stand and fall together.

3) Regarding Issue 3, claims 1 and 7-9 stand and fall together, and claims 3-6 stand and fall together.

Argument

A. Summary of the Argument

Two independent claims and their associated dependent claims are pending in this appeal: independent claim 1 and claims 7-9 dependent thereon, and independent claim 3 and claims 4-6 dependent thereon. Each rejection applied to these claims is erroneous and should be reversed for the reasons summarized below.

1. Claims 1 and 7-9.

Independent claim 1 and its dependent claims 7-9 are directed to a stent graft having one or more stents and a collagenous, remodelable sleeve covering. The sleeve

has "a length about equal to twice the length" of the stent(s) of the graft. A first portion of the sleeve "extends along and complements inside surface of" the stent(s) and a second portion is "folded back over a proximal end" of the stent(s) "and then along an outside surface" of the stent(s) to the distal end thereof. The first and second portions of the sleeve "are secured to at least the distal end" of the stent(s).

The Examiner made two obviousness rejections of claims 1 and 7-9. The first relied upon a single-reference (Babbs), which the Examiner admitted fails to teach securing the first and second sleeve portions to the distal end of a stent. Rather, Babbs teaches positioning the sleeve ends midway along the length of the stent, and attaching them to each other with a circumferential sutured seam. In an attempt to fill the admitted shortcomings of the reference, the Examiner asserted that the claimed end attachment features would be "an obvious design choice". The rejection made is in error because it:

- Disregards established case law holding that it is improper for the Patent Office to characterize a claimed feature as an "obvious design choice" when the feature is structurally and functionally different from the prior art;
- Does not even attempt to show positive motivation in the prior art to modify the reference to reach the claimed feature;
- Improperly excludes advantages of the claimed invention pointed out by Applicants' representative from the obviousness analysis, on the Examiner's stated basis that the advantages are not discussed in the specification, in direct contravention of established case law expressly holding that such requirement does not exist;
- Improperly relies upon conclusory allegations concerning the Examiner's "belief" about how the claimed invention would perform compared to the prior art as a basis for the rejection, in direct conflict with express admonitions in the MPEP and case law against doing so.

It is believed that any one of these errors would render the rejection improper, but when compounded they render the rejection particularly untenable. The rejection should thus be reversed.

In the second obviousness rejection of claims 1 and 7-9, the Examiner cited the combination of Gregory in view of Douglas. The Examiner admitted that the primary reference (Gregory) fails to "disclose that the first and second portions [of the sleeve] are secured to at least the distal end of the stent". The remainder of the rejection is then devoid of any further reference to this missing element, and in particular any assertion that this missing element would be motivated by the prior art. This rejection thus fails on its face to establish that the claims are *prima facie* obvious. Further, it would appear that any attempt to "repair" this rejection would bear the same infirmities discussed above in connection with the Babbs rejection. This is because like Babbs, Gregory teaches a sleeve with ends drawn to the midline of the stent and sewn together, rather than an end securement feature as claimed. Still further, the sleeve material of the claims is remodelable. Neither of the cited references teaches this feature, nor did the Examiner even assert so. Thus, even if combined, the references do not reach the claimed invention. Accordingly, this second rejection of claims 1 and 7-9 is also untenable and should be reversed.

2. Claims 3 and 4-6

Claim 3 and its dependent claims 4–6 are directed to stent graft which includes *inter alia* "a plurality of stents connected together to form a stent frame with lumens of the respective stents co-aligned to form common continuous lumen" and a remodelable collagenous covering "extending therealong between the proximal and distal stent frame ends". The covering is a sleeve initially having a length about equal to twice the length of the multi-stent frame and has a first portion extending along and complimenting the inside surface of the multi-stent frame and a second portion folded back over a proximal end of the multi-stent frame and then along an outside surface to the distal end of the multi-stent frame.

The Examiner made two obviousness rejections of these claims. A first rejection cited a combination of Babbs in view of Douglas. In it, the Examiner relied primarily upon Babbs as teaching elements of the claims but admitted that Babbs "does not disclose a plurality of stents connected to each other". The Examiner then relied upon a bifurcated multi-stent structure of Douglas for this teaching. This rejection fails to establish the claims as *prima facie* obvious because (i) assuming *arguendo* the references are combinable they fall short of the claimed elements, (ii) the references are in fact not properly combinable as asserted by the Examiner because the cylindrical sleeve wrap taught by Babbs would simply not work on the bifurcated multi-stent structure of Douglas; and (iii) the claimed stent graft structure provides advantages undisclosed by the references individually or in combination. Particularly:

- As to point (i), Babbs teaches using a sleeve twice as long as a single stent. Babbs does not teach using a sleeve twice as long as a string of connected stents, nor does the Examiner even assert so. Thus even if it could be made, the Babbs/Douglas combination would result in a string of individually wrapped stents, distinct from the claims.
- As to point (ii), the Douglas multi-stent graft structure is bifurcated, having two smaller lumen legs opening into a larger lumen section. The simple cylindrical sleeve of Babbs simply could not be arranged with the bifurcated stent structure of Douglas to arrive at a sleeve-sandwiched stent graft structure as claimed.
- As to point (iii), the claimed stent graft structure having a single remodelable sleeve extending along the inner and outer surfaces of the multi-stent frame enables the presentation of smoother inner and outer surfaces along the graft than would occur with individually wrapped stents. On the inside, this can provide improved flow properties through the stent graft lumen. On the outside, this can (1) provide improved uniform contact of the remodelable material with the area being treated as

opposed to having discontinuities in covering material where stents meet; (2) enable minimization of presentation of foreign body materials (e.g. sutures of the covering and/or filaments connecting adjacent stents) along the length of the stent graft which are known to cause inflammatory foreign body responses that could interfere with desired remodeling processes promoted by the sleeve covering; and (3) minimize the risk of leakage of blood through the covering which might occur through multiple seams along the length of the multi-stent graft.

For these reasons the rejection of claims 3-6 over Babbs in view of Douglas is erroneous and should be reversed.

In the second rejection of claims 3-6, the Examiner cited the combination of Gregory in view of Douglas. However, the sleeve material of the claims is remodelable. Neither of the cited references teaches this feature, nor did the Examiner even assert so. Thus, even if these two references could be combined, they do not reach all elements of the claimed invention. Moreover, in the rejection, the Examiner relied primarily upon Gregory, but admitted that Gregory "does not disclose a plurality of stents connected to each other" (this rejection is very similar in this respect to the Babbs/Gregory rejection discussed above). The Examiner then relied upon a multi-stent structure of Douglas for this teaching. This rejection also fails for all of the reasons noted above as to the Babbs/Gregory rejection. As noted above, Gregory is like Babbs in its teachings relative to the covering sleeve. Thus, this attempted combination fails to establish the claims as *prima facie* obvious because (i) even assuming *arguendo* the references are combinable, the combination results in a string of individually wrapped stents, distinct from the claims (see first bullet immediately above); (ii) the references are in fact not properly combinable as asserted by the Examiner because the cylindrical sleeve wrap taught by Gregory would simply not work on the bifurcated multi-stent structure of Douglas (see second bullet immediately above); and (iii) the claimed stent graft structure provides advantages undisclosed by the references individually or in combination (see third bullet immediately above).

For these reasons the rejection of claims 3 and 4-6 over Gregory and Douglas is also in error and should be reversed.

B. An Overview of Pertinent Obviousness Law

When rejecting claims under 35 U.S.C. § 103, "the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art." In re Fritch, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992).[1] To establish a *prima facie* case of obviousness, the Examiner must provide objective evidence 1) of some suggestion or motivation to combine or modify one or more prior art references,[2] 2) that the suggested combination or modification has a reasonable expectation of success,[3] and 3) that the prior art reference or references, when combined, suggest or teach all of applicant's claim limitations. MPEP § 2143. As held by the Federal Circuit, "[t]hese findings or evidence must be specific, clear, and particular." In re Lee, 61 U.S.P.Q. 2d 1430, 1433-34 (Fed. Cir. 2002). "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not [considered sufficient] 'evidence'[4]" to support a finding of *prima facie* obviousness. In re Dembiczak, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999); See also, Ex Parte Levengood, 28 U.S.P.Q. 2d 1300, 1301 (Bd. Pat. App. & Int. 1993).

Obviousness determinations must be performed without "entry into the 'tempting but forbidden zone of hindsight.'" Dembiczak, 50 U.S.P.Q. 2d at 1616 (Fed. Cir. 1999).[5] More specifically, in Dembiczak, the Federal Circuit offered the following guidance:

---

[1] Citing In re Piasecki and Meyers, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984).

[2] This motivation must be found in the references or within the body of knowledge available to a person of ordinary skill in the art at the time applicant's invention was conceived. See, MPEP § 2142.

[3] "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure." In re Vaeck, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991) (citing In re Dow Chemical Co., 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988)).

[4] E.g., McElmurry v. Arkansas Power & Light Co., 995 F.2d 1576, 1578, 27 U.S.P.Q. 2d 1129, 1131 (Fed. Cir. 1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact.") [citation omitted].

[5] Quoting Loctite Corp. v. Ultraseal Ltd., 228 U.S.P.Q. 90, 98 (Fed. Cir. 1998) (overruled on other grounds).

> [m]easuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.[6] . . .

Dembiczak, 50 U.S.P.A. 2d at 1617.[7] The best protection against the use of hindsight is a rigorous application of the motivation to combine criterion, which results in most *prima facie* obviousness determinations hinging on an objective finding of some motivation or suggestion to combine or modify one or more prior art references. See, Dembiczak, 50 U.S.P.Q. 2d at 1617; In re Roufett, 47 U.S.P.Q. 2d 1453, 1457-58 (Fed. Cir. 1998).

The Federal Circuit has identified three possible sources for evidencing a motivation to combine or modify references, "the nature of the problem to be solved, the teachings of the prior art, [or] . . . the knowledge of persons of ordinary skill in the art." Roufett, 47 U.S.P.Q. 2d at 1457-58. In most obviousness determinations, evidence of a suggestion or motivation originates from the teachings of the pertinent prior art references. Dembiczak, 50 U.S.P.Q. 2d at 1617. This evidence of a motivation to modify the teaching of a reference[8] or combine the teachings of one or more references must be specific,[9] supported by particular objective findings[10] of a positive motivation[11]

---

[6] [citation omitted].

[7] Citing C.R. Bard, Inc. v. M3 Sys., Inc., 48 U.S.P.Q. 2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding.")).

[8] "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 U.S.P.Q. 2d 1313, 1316-17 (Fed. Cir. 2000) [citation omitted].

[9] "The need for specificity pervades this authority. [citation omitted]." In re Lee, 61 U.S.P.Q. 2d 1430, 1433-34 (Fed. Cir. 2002).

[10] "[T]he examiner can satisfy the burden of showing obviousness of the combination 'only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" In re Lee, 61 U.S.P.Q. 2d 1430, 1433-34 (Fed. Cir. 2002) (quoting In re Fritch, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992). "In other words, the [Examiner] . . . must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious." In re Rouffet, 47 U.S.P.Q. 2d 1453, 1459 (Fed. Cir. 1998).

to modify or otherwise combine references. In re Fine, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988); Lee, 61 U.S.P.Q. 2d at 1433-34.

The Examiner, when relying on a motivation to modify that originates within the general knowledge of one of ordinary skill in the art, must take care to make specific evidentiary findings regarding positive motivation. See, In re Goodwin, Margrave, and Wagner, 198 U.S.P.Q. 1, 3 (C.C.P.A. 1978); Fine, 5 U.S.P.Q. 2d at 1599; and MPEP § 2143.01. As summarized in the MPEP,

> [a] statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.

MPEP § 2143.01.[12] Further, it is improper for the Patent Office to reject a claim under 35 U.S.C. § 103 based upon the assertion that a claimed feature is merely a "design choice" when the structure and function of the feature differ from the prior art. In re: Chu, 36 U.S.P.Q. 2d, 1089 (Fed. Cir. 1995) ("finding of 'obvious design choice' precluded where the claimed structure and the function it performs are different from the prior art.") (citing In re: Gal, 980 F. 2d. 717, 25 U.S.P.Q. 2d 1076 (Fed. Cir. 1992). Still further, advantages or functional difference need not be discussed in the specification in order to be argued in support of patentability. To require an applicant to include evidence and arguments in the specification as to whether a claimed feature is a matter of design choice "would be to require patent applicants to divine the rejections the PTO will proffer when patent applications are filed." Chu, 36 U.S.P.Q. 2d 1089.

In the event the Examiner establishes a *prima facie* case of obviousness, applicants may submit rebuttal evidence to prove that the claim or claims are nonobvious.

---

[11] "'[T]eachings of references can be combined only if there is some suggestion or incentive to do so.'" In re Fine, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988) (quoting ACS Hosp. Sys. Inc. v. Montefiore Hosp., 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984)).

[12] Citing Ex parte Levengood, 28 U.S.P.Q. 2d 1300 (Bd. Pat. App. & Inter. 1993).

After rebuttal evidence is submitted, "[r]egardless of whether the *prima facie* case would have been characterized as strong or weak, the examiner must consider all of the evidence anew." In re Piasecki and Meyers, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). When evaluating rebuttal evidence, the Examiner must compare the claimed invention as a whole against the prior art references, rather than comparing components of the claimed invention to the prior art.[13] Additionally, in evaluating the obviousness of a claimed invention, the Examiner must also consider "objective evidence or secondary considerations." MPEP § 2141. For example, advantages directly flowing from the claimed invention are proper support for finding nonobviousness. Preemption Devices, Inc. v. Minn. Mining and Mfg. Co., 221 U.S.P.Q. 841, 844 (Fed. Cir. 1984) (citing Graham et al. v. John Deere Co. of Kan. City, 148 U.S.P.Q. 459 (U.S. 1966)).

C. Detailed Arguments

1. Claims 1 and 7-9 are Nonobvious Under 35 U.S.C. § 103 (a) Over Babbs (WO 98/25544).

The Examiner rejected claims 1 and 7-9 under 35 U.S.C. § 103 (a) as being obvious over a single reference, Babbs. When dealing with such rejections the Federal Circuit has advised: "[W]hen obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 U.S.P.Q. 2d 1313, 1316-17 (Fed. Cir. 2000). Further, evidence of a motivation to modify the teaching of the reference must be specific and supported with particular objective findings [Fine, 5 U.S.P.Q. 2d at 1599; Lee, 61 U.S.P.Q. 2d at 1433-34], and such obviousness determinations must be performed overall

[13] "In its argument that the invention here is but making integral what had earlier been made in four bolted pieces, Nortron seeks to limit the focus of inquiry to a structural difference from the prior art and then to show that that difference alone would have been obvious. That effort is not proper under the statute, which requires that an invention be considered 'as a whole' . . . ." Carl Schenck, A.G. v. Nortron Corp., 218 U.S.P.Q. 698, 700 (Fed. Cir. 1983).

without "entry into the 'tempting but forbidden zone of hindsight.'" Dembiczak, 50 U.S.P.Q. 2d at 1616.

In making this single reference obviousness rejection, the Examiner admitted that "Babbs et al. does not disclose that the first and second portions are secured to at least the distal end of the stent." Rather, the Babbs reference teaches a stent graft having a tubular covering that is wrapped around the inner and outer surfaces of the stent such that the ends of the tubular covering meet along the exterior portion of the stent at the stent's longitudinal midpoint. At the midpoint, each end of the covering material turns outwardly from the stent's exterior surface, forming a 90 degree angle with the stent surface, and is secured to one another with sutures. See Babbs, FIG. 2, PG. 12, line 29 through PG. 13, line 11. Additionally, Babbs teaches that when using such a midline sutured seam, "suturing the submucosal tissue to the individual coils of the stent is not necessary, [because] the single suture line is sufficient to secure the submucosal tissue in place." Babbs, PG. 16, lines 13-14.

Despite these teachings in Babbs away from a securement of a covering at an end of the stent, the rejection states in a conclusory fashion that this differentiating claim feature "would have been an obvious matter of design choice". In jumping to this conclusion, the Examiner neither cited any reference teaching that the claimed end attachment was an interchangeable substitute with the reference's midline circumferential sutured seam, nor offered any other evidence or official notice as to the general knowledge and availability of this "design choice" to those of ordinary skill in the art. This does not provide the "specific, clear and particular" finding needed to support a proper rejection under 35 U.S.C. § 103 [Lee, 61 U.S.P.Q. at 1433-34 (Fed. Cir. 2002)], but rather evidences the use of hindsight. Moreover, this approach appears to contradict the guidance in MPEP 2144.03: "It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection is based" (citing In re: Zurko, 258 F. 3d 1379, 59 U.S.P.Q. 2d 1693 (Fed. Cir. 2001); "[T]he Board cannot simply reach conclusions based on its own understanding or experience – or its own assessment of what would be basic knowledge

or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings"). Absent the ability to identify any motivation for securing the covering at a stent end as claimed, it is submitted that the Examiner's analysis represents an improper foray into the "tempting but forbidden zone of hindsight". Dembiczak, 50 U.S.P.Q. 2d at 1616.

Furthermore, the rejection's reliance upon Babbs and "an obvious design choice" fails because the claimed features differ structurally and functionally from those in the Babbs reference. See, Chu, 36 U.S.P.Q. 2d 1089; Gal, 25 U.S.P.Q. 2d 1076. Clearly, securement of the first and second portions of the sleeve covering to the end of the stent differs structurally from the midline circumferential seam connecting the sleeve ends taught in the Babbs reference. Clearly also, these structures differ functionally. In this regard, functional differences between the structures were pointed out by Applicants' attorney during previous prosecution. For example, in the Response dated June 4, 2004 immediately prior to the final rejection under appeal, the Applicants' attorney noted that the prior art construction would create a reduction in the diameter of the stent graft lumen at the location of the midpoint seam and present leakage risks, unlike the claimed invention. However, this discussion was glossed over and improperly disregarded in the present rejection. In alleged support, the Examiner stated (emphasis added):

> Regarding the advantage of the Applicant's invention stating that the sleeve is folded back over a proximal end and distal end of the at least one stent, the Examiner still believes that the Applicant's representative has not disclose [*sic*] in the specification the importance of having the second portion of the sleeve folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof and secured in the distal end.

See Final Action, page 5. This statement would appear to be in clear contravention of controlling case law on the point. There is no requirement that advantages of the invention be set forth in the specification, and to require Applicants to do so "would be to require patent applicants to divine the rejections the PTO will proffer when patent applications are filed". See, Chu, 36 U.S.P.Q. 2d 1089.

In further divergence from court and MPEP guidance upon proper § 103 analyses, the rejection is based upon conclusions made by the Examiner about Applicant's invention that are wholly unsupported by any evidence or line of technical reasoning. In the rejection, the Examiner stated that:

> Additionally, the Examiner believes that the Babbs reference will perform equally as well as the Applicant's stent graft.

See Final Action, page 5 (emphasis added). This statement compounds another similar allegation that:

> One of ordinary skill in the art would have expected Applicant's invention to perform equally well with the leading and trailing ends of the graft secured at the middle of the stent because no matter how the leading and trailing ends of the graft is *[sic]* secured, the final purpose of the implant is the same (biocompatibility).

See Final Action, sentence spanning pages 1-2.

As a first measure of response, these unsupported conclusions, used as a principal reasons for making and/or maintaining rejections, would appear to directly conflict with the direction given in MPEP 2144.03 and Zurko, 59 U.S.P.Q. 2d 1693 -- "[T]he Board cannot simply reach conclusions based on its own understanding or experience – or its own assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings".

Moreover, these conclusions are simply incorrect. The claimed end attachment features functionally distinguish the stent grafts from those of the prior art and provide advantages thereover. First, the stent grafts of Applicants' claims 1 and 7-9 provide an advantage over Babbs because Applicants' inventions do not require the presence of a circumferential series of sutures, a significant foreign body, in the middle of the remodelable material field. The claimed covering material includes a remodelable extracellular matrix material that is attached at the stent's distal end. The specification describes the extracellular matrix material as providing "a framework for cells that after

emplacement within a patient, becomes remodeled by host tissue and degrades and reabsorbs over time." Application, PG. 5, lines 2-5. The covering material of Babbs forms a midpoint seam along the tissue contacting side of the stent. The covering material is secured at the seam with a sizable series of sutures placed through each end of the covering material that forms the seam. The presence of this mass of sutures at the midpoint of the Babbs structure can initiate a foreign body response in that area upon implantation in a patient. This foreign body response can deleteriously affect or detract from the healing and remodeling process that is induced by the remodelable covering material. The absence or minimization of foreign body material at the stent's midpoint as enabled by the present invention can lead to more effective tissue ingrowth and remodeling.

Additionally, the stent grafts of Applicants' claims 1 and 7-9, with the inner and outer covering portions secured to the distal end of the stent frame, provide an advantage over Babbs because they do not require a mid-stent circumferential seam to hold the covering around the stent(s), and thus will avoid the need for a seam with outlying suture material as shown in Babbs that would form an obstruction or irregularity within the stent graft lumen when the device is implanted in a patient. In this regard, the external midpoint seam of Babbs can force a reduction in stent graft internal diameter at those portions of the stent graft that surround or encompass the midpoint seam after the stent graft is implanted within a bodily lumen. This inner obstruction can deleteriously impact flow through the stent graft lumen.

Further, the stent grafts of Applicants' claims 1 and 7-9 provide an advantage over Babbs in that they do not require a midpoint circumferential seam which creates risk of leakage into an aneurysm intended to be excluded by the stent graft. In particular, in the event that blood enters the interstitial area formed by the covering, the midpoint seam design of Babbs will necessarily present risks relating to the leakage of blood from within the interstitial space into the excluded aneurismal pocket. This counteracts the purpose of the stent graft in excluding the aneurysm. Because Applicants' covering sleeve material is attached at the distal end of the stent, no midpoint circumferential seam is required and

thus the stent grafts can be designed to minimize or eliminate leakage through the central section of the graft, which would commonly overlie an aneurismal pocket in such a repair.

Additionally, the Examiner's obviousness rejection of claims 1 and 7-9 is improper because he failed to consider the claimed invention as a whole, including any and all advantages which flow there from. As note above, the Federal Circuit has held that "[i]t is entirely proper . . . to take into account advantages directly flowing from the invention patented," when evaluating obviousness under § 103. Preemption Devices., 221 U.S.P.Q. at 844. When asserting such advantages that directly flow from the claimed invention, an applicant is not solely limited to evidence and arguments contained within the specification. Chu, 36 U.S.P.Q. 2d at 1094. Applicants' claimed inventions provide the above-noted advantages over Babbs, each of which flow from the invention claimed and provide further reason to conclude that the claimed inventions are nonobvious in view of Babbs.

In summary, claims 1 and 7-9 are not obvious over Babbs. The Examiner has failed to set forth a specific suggestion or motivation, either in the nature of the problem to be solved, in the teachings of Babbs, or within the general knowledge of one of ordinary skill in the art, to modify Babbs into a configuration where the covering material is attached at a stent end as claimed. Additionally, the inventions of claims 1 and 7-9 provide several advantages over the Babbs design, each of which supports a finding that Applicants' inventions are nonobvious. Therefore, Applicants respectfully submit that the rejection of claims 1 and 7-9 in view of Babbs is improper and should be reversed.

2. *Claims 3-6 are Nonobvious Under 35 U.S.C. § 103 (a) Over Babbs (WO 98/25544) in View of Douglas (U.S. Pat. No. 6,090,128).*

The Examiner rejected claims 3-6 under 35 U.S.C. § 103 (a) as being unpatentable over Babbs in view of Douglas. In making his rejection, the Examiner cited the above-discussed Babbs reference, and Fig. 2 of Douglas which shows a bifurcated

stent graft structure having two smaller legs opening into a bigger tubular section. Thus, the Examiner's rejection relied upon an attempted substitution of a multi-stent structure in the prior art for the single-stent structure disclosed in Babbs. However, it is clear that this attempted combination fails to render the present claims obvious. The rejection does not explain or attempt to explain how one would take the single cylinder sleeve disclosed in Babbs and route it through the bifurcated structure of Douglas in order to reach the claimed limitations. In fact, this would not appear to be possible due to the bifurcated nature of the Douglas multi-stent structure and the fact that the lumen sizes of the legs or limbs and the larger section of the Douglas graft differ significantly and thus major modification of the sleeve of Babbs would be needed to even attempt to line the inner and outer surfaces of the entire Douglas structure. Moreover, even if the combination of the two references could be made, one would not arrive at the claimed structure. Babbs teaches a sleeve material that is only long enough to cover the inner and outer surfaces of a single stent. Nowhere does Babbs teach making a sleeve material long enough to encompass more than one stent, nor does the Examiner's rejection set forth any such assertion or any basis for making any such an assertion. Accordingly, should one be able to combine the teachings of Babbs and Douglas, one would end up with a situation in which each stent was individually covered. This is in direct contrast to the present claims in which the sleeve material is long enough to travel inside and outside the multi-stent graft frame and completely cover the frame as a single unit. Still further, claim 3 requires that the stent frame be formed from "respective stents co-aligned to form a common continuous lumen extending from a distal stent frame end to a proximal stent frame end, and the covering extending therealong between the proximal and distal stent frame ends." The multi-stent structure of Douglas does not meet this limitation because when considered from its first end to its second end, the lumens of the respective stents of the structure are not co-aligned. Rather, at one end stents having much smaller lumens are provided (forming the limbs of the graft) and at the other end stents of much larger lumens are provided. The resulting structure from the alleged combinations of references would thus not provide the features of the claim, even if it could be made.

As provided in the MPEP (see 706.02(j)) an Examiner should set forth in the Office Action, as a part of an obviousness rejection, the proposed modifications of the applied reference(s) necessary to arrive at the claimed subject matter, and an explanation why one of ordinary skill in the art at the time of the invention was made would have been motivated to make the proposed modification. In making the above rejection, the Examiner has not even addressed the modification necessary to the Babbs reference in terms of providing a sleeve long enough to encompass multiple stents, either as a modification needed or much less providing an explanation of why that modification would be motivated in a positive sense from the references. Further, the Examiner has not proposed or explained how one skilled in the art would apply the sleeve covering material of Babbs to the bifurcated structure of Douglas to reach the claimed features, and in fact this application would not appear to be possible absent some modification of multi-stent structure or the covering material, again neither of which were discussed in the Action in terms of their being necessary or motivated by the prior art itself. This is contrary to the established principles that findings of motivation to combine references must be specific and objectively stated. See, Fine, 5 U.S.P.Q. 2d 1596 at 1599; Lee, 61 U.S.P.Q. 2d at 1433-34. Accordingly, the Examiner has failed to set forth a *prima facie* case of obviousness as to claims 3-6 over the Babbs/Douglas combination.

Additionally, this obviousness rejection of claims 3-6 is improper because fails to take into account the claimed inventions as a whole, including any and all advantages which flow therefrom. The federal Circuit has held that it is entirely proper to take into account advantages directly flowing from the claimed invention when evaluating obviousness [Preemption Devices, 221 U.S.P.Q. at 844], and that when asserting advantages that directly flow from the claimed invention, an applicant is not solely limited to evidence and arguments contained within the specification. Chu, 36 U.S.P.Q. 2d 1089 at 1094. Applicants' claimed inventions provide at least the following advantages over the references, each of which flow directly from the inventions claimed and provide further buttress to the conclusion that the claimed inventions are nonobvious over Babbs in view of Douglas.

First, the claimed features which have the sleeve covering the multiple-stent graft structure provides the ability to encompass and cover the connected portions of the multiple stents, including any materials such as filaments or other structures used in the connection, which can present foreign bodies that could interfere with the desired remodeling function of the covering as it contacts bodily lumen surfaces. For example, an overall stent graft having multiple stents each separately covered by its own sleeve material, with each segment of covering material attached in a circumferential midline suture line as disclosed in Babbs, would present multiple instances of such seams and suture lines upon the length of the graft material. Second, with separate sleeve segments covering each stent in the overall structure, surface irregularities would be introduced in between stents as one transitions to the other, which in accordance with the claimed invention can be minimized by the surfaces of the all-encompassing sleeve traveling over top and covering the transition point from one stent to the next. Third, the unitary sleeve covering the multi-stent structure in accordance with claims 3-6 will participate in unifying the overall stent graft structure. These effects could not be achieved if one followed the teachings of the Babbs/Gregory combination and separately encompassed each stent in the structure with its own sleeve segment.

In summary, claims 3-6 are not obvious over Babbs in view of Douglas. The subject rejection based on these references fails to set forth a proper basis for combining these references, or to establish that even if combine the references would meet all elements of claims 3-6. Additionally, the inventions of claims 3-6 provide advantages over the references which further support a finding that Applicants' inventions are nonobvious. Therefore, Applicants submit that the Examiner's rejection of claims 3-6 is in error and should be reversed.

3. Claims 1 and 3-9 are Nonobvious Under 35 U.S.C. § 103 (a) Over Gregory (U.S. Pat. No. 5,990,379) in View of Douglas (U.S. Pat. No. 6,090,128).

The Examiner rejected claims 1 and 3-9 under 35 U.S.C. § 103 (a) as being unpatentable over Gregory in view of Douglas. In making his rejection, the Examiner cited the above-noted sections of the Douglas reference, as well as FIGS. 8-10 of Gregory, which show the manufacture of a single covered stent wherein a covering sleeve material is circumferentially sutured at a mid-position along a single stent (like Babbs). This rejection suffers all of the inadequacies of the rejections discussed above, plus more. These inadequacies are separately discussed below for claims 1 and 7-9 dependent thereon, and claim 3 and claims 4-6 dependent thereon.

a. Claims 1 and 7-9 are Nonobvious Under 35 U.S.C. § 103 (a) Over Gregory (U.S. Pat. No. 5,990,379) in View of Douglas (U.S. Pat. No. 6,090,128).

As detailed below, the stated rejection of claims 1 and 7-9 over the combination of Gregory in view of Douglas fails to establish a *prima facie* case of obviousness. Such a case requires that an Examiner, among other things, provide objective evidence that when combined, the references relied upon suggest or teach all of Applicants' claim limitations. MPEP § 2143. These findings or evidence must be specific, clear and particular. Lee, 61 U.S.P.Q. 2d at 1433-34. Broad conclusory statements regarding the teaching of multiple references are not sufficient. Dembiczak, 50 U.S.P.Q. 2d at 1617. The rejection at issue fails to comply with these standards and is thus in error.

To begin with, in making this rejection, the Examiner acknowledged that the primary reference, Gregory, "does not disclose that the first and second portion [of the covering sleeve] are secured to at least the distal end of the stent". This point was then never again addressed in the rejection. Thus, without setting forth a proposed modification of the references to arrive at this claimed feature, and without an explanation why one of ordinary skill in the art would have been motivated to make the proposed modification, the Examiner nonetheless rejected claims 1 and 7-9, which include this feature.

Further, the covering sleeve of the present claims is remodelable by host tissues. Neither the Gregory nor the Douglas reference teaches this feature, nor did the Examiner assert so. Accordingly, this reference combination could not possibly suggest all of the elements presently claimed, as required for a proper rejection.

Moreover, the obviousness rejection of claims 1 and 7-9 is improper because it failed to take into account the claimed inventions as a whole, including any and all advantages which flow there from. As noted above, the pertinent case law provides that such advantages support a finding of nonobviousness, and need not be set forth in the specifications to be considered.

The primary Gregory reference, which the Examiner relies upon for aspects of the covering material, teaches a stent graft having a tubular covering material that is wrapped around the inner and outer surfaces of the stent such that each end of the tubular covering meets along the exterior portion of the stent at the stent's longitudinal midpoint. At the stent's midpoint, one end of the covering material overlaps the other end and the two ends, or layers, are secured to one another with a series of sutures that extend around the circumference of the stent's frame. Gregory, FIG. 10, Col. 14, lines 36-39. Applicants' claimed invention provides the following advantages over this teaching, each of which flow from the inventions claimed and provide further support that the claimed inventions are nonobvious over Gregory in view of Douglas.

First, the stent grafts of Applicants' claims 1 and 7-9 provide an advantage over the Gregory/Douglas combination because Applicants' inventions do not require the presence of a circumferential series of sutures, a significant foreign body, in the middle of the remodelable material field. The claimed covering material includes a remodelable extracellular matrix material that is attached at the stent's distal end. The specification describes the extracellular matrix material as providing "a framework for cells that after emplacement within a patient, becomes remodeled by host tissue and degrades and reabsorbs over time." Application, PG. 5, lines 2-5. The covering material of the primary Gregory reference forms a midpoint seam along the tissue contacting side of the stent. The covering material is secured at the seam with a series of sutures placed

through each end of the covering material that forms the seam. The presence of these sutures at the midpoint can initiate a foreign body response in that area upon implantation in a patient. This foreign body response can deleteriously affect or detract from the healing and remodeling process that is induced by the claimed remodelable covering material. The absence or minimization of foreign body material at the stent's midpoint as enabled by the present invention can lead to more effective tissue ingrowth and remodeling.

Additionally, the stent grafts of Applicants' claims 1 and 7-9, with the inner and outer covering portions secured to the distal end of the stent frame, provide an advantage over the Gregory/Douglas combination because they do not require a mid-stent circumferential seam to hold the covering around the stent(s), and thus will avoid the need for a seam with outlying suture material that would form an obstruction or irregularity within the stent graft lumen when the device is implanted in a patient. In this regard, the external midpoint seam of the primary Gregory reference can force a reduction in stent graft internal diameter at those portions of the stent graft that surround or encompass the midpoint seam after the stent graft is implanted within a bodily lumen. This inner obstruction can deleteriously impact flow through the stent graft lumen.

Further, the stent grafts of Applicants' claims 1 and 7-9 provide an advantage over the Gregory/Douglas combination in that they do not require a midpoint seam which creates risk of leakage into an aneurysm intended to be excluded by the stent graft. In particular, in the event that blood enters the interstitial area formed by the covering, the midpoint seam design will necessarily present risks relating to the leakage of blood from within the interstitial space into the excluded aneurismal pocket. This counteracts the purpose of the stent graft in excluding the aneurysm. Because Applicants' covering sleeve material is attached at the distal end of the stent, no midpoint seam is required and thus the stent grafts can be designed to minimize or eliminate leakage through the central section of the graft, which would commonly overlie an aneurismal pocket in such a repair.

In summary, claims 1 and 7-9 are not obvious over Gregory in view of Douglas. Even if combined, these references do not teach all of the limitations of claims 1 and 7-9. Moreover, the Examiner's basis for the rejection acknowledges that the references, even if combined, fail to teach a claimed feature, but does not provide objective evidence as to why that feature would be taught or suggested to the ordinarily skilled artisan. Further, the stent grafts of claims 1 and 7-9 provide advantages that buttress a conclusion of nonobviousness. Accordingly, it is submitted that this rejection is erroneous and should be reversed.

b. Claims 3-6 are Nonobvious Under 35 U.S.C. § 103 (a) Over Gregory (U.S.Pat. No. 5,990,379) in View of Douglas (U.S. Pat. No. 6,090,128).

As detailed below, the stated rejection of claims 3-6 over the combination of Gregory in view of Douglas fails to establish a *prima facie* case of obviousness. Such a case requires that an Examiner, among other things, provide objective evidence that there is proper motivation to combine the references, and that if combined, the references relied upon suggest or teach all of Applicants' claim limitations. MPEP § 2143. These findings or evidence must be specific, clear and particular. Lee, 61 U.S.P.Q. 2d at 1433-34. Broad conclusory statements regarding the teaching of multiple references are not sufficient. Dembiczak, 50 U.S.P.Q. 2d at 1617. This rejection of claims 3-6 fails to comply with these standards and is thus in error.

First, the covering sleeve of the present claims is remodelable by host tissues. Neither the Gregory nor the Douglas reference teaches this feature, nor does the Examiner assert so in making this rejection. Accordingly, this combination could not possibly suggest all of the elements presently claimed as required for a proper rejection.

Second, in making this rejection, the Examiner asserted that it would have been obvious to use a multi-stent structure as suggested by Douglas in place of the single stent of Gregory. However, as discussed above with respect to the Examiner's attempt to combine Babbs and Douglas, this approach simply doesn't work. The multi-stent

structure of the Douglas reference defines a bifurcated graft device. The Examiner has not explained or attempted to explain how one would take the single cylinder sleeve material disclosed in Gregory and route it through the bifurcated structure of Douglas in order to reach the claimed limitations. In fact, this would not appear to be possible due to the bifurcated nature of the Douglas multi-stent structure and the fact that the lumen sizes of the legs or limbs and the larger section of the Douglas graft differ significantly and thus major modification of the sleeve or covering material of Gregory would be needed to even attempt to line the inner and outer surfaces of the entire Douglas structure. Moreover, even if the combination of the two references could be made, one would not arrive at the claimed structure. Gregory teaches a sleeve material that is of a length about twice that of a single stent. Nowhere does Gregory teach making a sleeve material long enough to encompass more than one stent, nor does the Examiner's rejection set forth any such assertion or any basis for making any such an assertion. Accordingly, should one be able to combine the teachings of Gregory and Douglas, one would end up with a situation in which each stent was individually covered in accordance with Gregory. This is in direct contrast to the present claims in which the sleeve material is long enough to travel inside and outside the multi-stent graft frame and completely cover the frame as a single unit. Still further, claim 3 requires that the stent frame be formed from "respective stents co-aligned to form a common continuous lumen extending from a distal stent frame end to a proximal stent frame end, and the covering extending therealong between the proximal and distal stent frame ends." The multi-stent structure of Douglas does not meet this limitation because when considered from its first end to its second end, the lumens of the respective stents of the structure are not co-aligned. Rather, at one end stents having much smaller lumens are provided (forming the limbs of the graft) and at the other end stents of much larger lumens are provided. The resulting structure from the alleged combinations of references would thus not provide the features of the claim, even if it could be made.

As provided in the MPEP (see 706.02(j)) an Examiner should set forth in the Office Action, as a part of an obviousness rejection, the proposed modifications of the

applied reference(s) necessary to arrive at the claimed subject matter, and an explanation why one of ordinary skill in the art at the time of the invention was made would have been motivated to make the proposed modification. In making the above rejection, the Examiner has not even addressed the modification necessary to the Gregory reference in terms of providing a sleeve long enough to encompass multiple stents either as a modification needed or by providing an explanation of why that modification would be motivated in a positive sense from the references. Further, the Examiner has not proposed or explained how one skilled in the art would apply the sleeve covering material of Gregory to the bifurcated structure of Douglas to reach the claimed features, and in fact this application would not appear to be possible absent some modification of multi-stent structure or the covering material, again neither of which were discussed in the Action in terms of their being necessary or motivated by the prior art itself. Accordingly, the Examiner has failed to set forth a *prima facie* case that claims 3-6 are obvious over the combination of Gregory and Douglas.

Additionally, the Examiner's obviousness rejection of claims 3-6 is improper because he failed to consider the claimed inventions as a whole, including any and all advantages which flow there from. Applicants' claimed inventions provide at least the following advantages over the references, each of which flow directly from the inventions claimed and provide proof that the claimed inventions are nonobvious over Gregory in view of Douglas.

The claimed features which have the sleeve covering the multiple-stent graft structure provides the ability to encompass and cover the connected portions of the multiple stents, including any materials such as filaments or other structures used in the connection, which can present foreign bodies that could interfere with the desired remodeling function of the covering as it contacts bodily lumen surfaces. For example, an overall stent graft having multiple stents each separately covered by its own sleeve material, with each segment of covering material attached in a circumferential midline suture line as disclosed in Gregory, would present multiple instances of such seams and suture lines upon the length of the graft material. Moreover, with separate sleeve

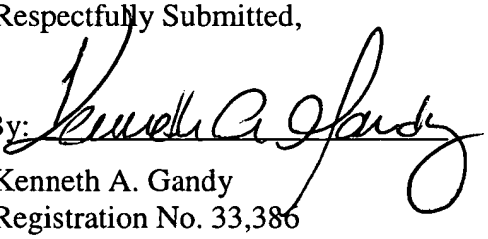
segments covering each stent in the overall structure, surface irregularities would be introduced in between stents as one transitions to the other, which in accordance with the claimed invention can be minimized by the surfaces of the all-encompassing sleeve traveling over top and covering the transition point from one stent to the next. Still further, the unitary sleeve covering the multi-stent structure in accordance with claims 3-6 will participate in unifying the overall stent graft structure.

In summary, claims 3-6 are not obvious over Gregory in view of Douglas. The subject rejection based on these references fails to set forth a proper basis for combining these references, or to establish that even if combined the references would meet all elements of claims 3-6. Additionally, the inventions of claims 3-6 provide advantages over the references which undergird a conclusion that Applicants' inventions as set forth in claims 3-6 are nonobvious. Therefore, Applicants submit that the Examiner's rejection of claims 3-6 is in error and should be reversed.

Conclusion

For the above reasons, the Examiner's rejections of claims 1 and 3-9 under 35 U.S.C. § 103 (a) are in error and should be reversed. Applicants thus respectfully request reversal of the present rejections and passage of the present application to issuance.

Respectfully Submitted,

By: 

Kenneth A. Gandy
Registration No. 33,386
Woodard, Emhardt, Moriarty,
McNett & Henry, LLP
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456

Appendix

Copy of Claims on Appeal

WHAT IS CLAIMED IS:

1. (Previously Amended) A stent graft comprising:

at least one stent having a proximal end and a distal end and having a lumen extending therethrough between the proximal and distal ends, and

a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue, secured to the at least one stent and extending therealong between the proximal and distal ends, wherein the covering is a sleeve that initially has a length about equal to twice the length of the at least one stent, a first portion of the sleeve extends along and complements inside surface of the at least one stent, and a second portion of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof, and wherein the first portion and the second portion of the sleeve are secured to at least the distal end of the at least one stent.

2. (Canceled)

3. (Previously Amended) A stent graft comprising:

at least one stent having a proximal end and a distal end and having a lumen extending therethrough between the proximal and distal ends, and

a covering of collagen having an isolated extracellular matrix layer that becomes remodeled by host tissue, secured to the at least one stent and extending therealong between the proximal and distal ends, wherein the covering is a sleeve that initially has a length about equal to twice the length of the at least one stent, a first portion of the sleeve extends along and complements inside surface of the at least one stent, and a second portion of the sleeve is folded back over a proximal end of the at least one stent and then along an outside surface of the at least one stent to the distal end thereof, wherein the stent graft further comprising a plurality of stents connected together to form a stent frame with lumens of the respective stents coaligned to form a common continuous lumen extending from a distal stent frame end to a proximal stent frame end, and the covering extending therealong between the proximal and distal stent frame ends.

4. (Original) The stent graft of claim 3, wherein the stent frame has eyelets at the proximal and distal ends.

5. (Original) The stent graft of claim 4, wherein the covering is sutured to the stent frame using a filament of biocompatible material that extends through the eyelets.

6. (Original) The stent graft of claim 3, wherein each of said plurality of stents has eyelets at proximal and distal ends thereof, and the covering is sutured to the stent frame using a filament of biocompatible material that extends through the eyelets.

7. (Original) The stent graft of claim 1, wherein the covering is secured to the at least one stent at locations along the stent using a filament of biocompatible material, the locations being adapted to secure the filament in position against movement axially with respect to the stent during deployment at a treatment site of a patient.

8. (Original) The stent graft of claim 1, wherein the covering is a sleeve of small intestine submucosa material.

9. (Original) The stent graft of claim 8, wherein the sleeve is defined by connecting together along a seam, opposite edges of at least one flat tissue of the small intestine submucosa material.

10. (Canceled)

11. (Canceled)